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10/565,064	07/07/2006	Peter John Houzego	PC32749A	6152

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EXAMINER	
SKORUPA, VALERIE LYNN	
ART UNIT	PAPER NUMBER
3771	

NOTIFICATION DATE	DELIVERY MODE
12/09/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/565,064	HOUZEGO, PETER JOHN	
	Examiner	Art Unit	
	VALERIE SKORUPA	3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-53* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,9,12-17,20-27,33-42,48-50 and 52* is/are rejected.

7)☒ Claim(s) *7,8,10,11,18,19,28-32,43-47,51 and 53* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 January 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *07/07/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. Claims 7, 8, 10, 11, 18, 19, 28-32, 43-47, 51, and 53 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 6 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. As to claim 6, a broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a

required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 6 recites the broad recitation "the angle between the flow paths is less than 45 degrees", and the claim also recites "and preferably less than 30 degrees" which is the narrower statement of the range/limitation.

Claim 12 recites the limitation "wherein the supports are" in line 6. There is insufficient antecedent basis for this limitation in the claim. Specifically, it is unclear whether Applicant is attempting to claim one support or multiple supports since only "a support" (line 3) has been claimed thus far.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Newell et al. (US Patent No. 4,811,731).

As to claim 1, Newell discloses a device (Fig. 1) for dispensing individual doses of powder from respective pockets of a carrier, the device including: a support 3 for a carrier 5 having a plurality of pockets containing respective doses of powder (col. 3, ln. 35-39); and a mouthpiece 27 through which to inhale an airstream carrying a dose of

powder (col. 4, ln. 13-17); the device further including walls 32 for defining individual respective first flow paths downstream of each respective pocket of a supported carrier wherein each individual respective first flow path is defined entirely by respective walls unique to that individual respective first flow path, is for connecting the corresponding respective pocket to the mouthpiece 27 and is for deaggregating powder in the airstream (col. 5, ln. 21-29).

As to claim 2, Newell discloses the claimed invention (as discussed in claim 1 above) including an arrangement 60 (Fig. 6) for moving individually each pocket from a respective storage position to a respective discharge position, wherein each pocket, in the respective discharge position, forms an integral part of the individual respective first flow path (col. 4, ln. 43-59).

As to claim 3, Newell discloses the carrier 5 has pockets provided with a lidding sheet (col. 1, ln. 50-57), the device allowing the lidding sheet to be ruptured as a consequence of moving a pocket from a respective storage position to a respective discharge position (col. 4, ln. 31-46).

As to claim 4, Newell discloses walls defining a second flow path 28 ("apertures", Fig. 1, Fig. 4) connecting with the mouthpiece and bypassing the pockets (col. 4, ln. 15-17).

7. Claim 9 is rejected under 35 U.S.C. 102(b) as being anticipated by Cox (US Patent No. 5,657,749).

As to claim 9, Cox discloses a device (Fig. 12) for dispensing a dose of powder from a pocket of a carrier including: a support 408/410; and a mouthpiece 400; the

device further including: walls defining first 402 and second 406 flow paths communicating with the mouthpiece 400, the first flow path 402 communicating with the pocket 412 of the supported carrier and the second flow path 406 bypassing the pocket 412; wherein the walls defining the first flow path 406 include, upstream of the pocket 412, a relatively reduced cross-sectional area (see illustrated Fig. 12 below, col. 7, ln. 31-58).

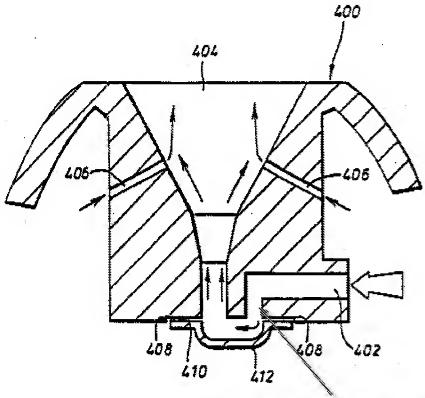

FIG. 12

8. Claims 12-17, 20, and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Braithwaite (WO 01/17595 A1).

As to claim 12, Braithwaite discloses a device for dispensing individual doses of powder from respective pockets of a pair of carriers (Fig. 7), the device including: a support 106 for two disc shaped carriers 101a/101b, each disc shaped carrier having at least one substantially planar first side surface (see Fig. 7) having an annular array of cavities 102 in which respective pockets are formed and a respective first lidding sheet (top of 101a/101b) sealed to the first side surface for enclosing the cavities, wherein the support 106 is for rotatably supporting the carriers 101a/101b about a substantially common axis (page 8, ln. 13 - page 9, ln. 4); a mouthpiece (page 13, ln. 28) through which to inhale an airstream carrying powder from the carriers; a dispensing mechanism 121 for releasing into the airstream the powder of a respective pocket of a supported carrier (page 9, ln. 26-28); and an indexing mechanism 107 for rotating the carriers relative to the dispensing mechanism so as to enable powder to be released from different pockets (page 8, ln. 14-16).

As to claim 13 and 14, Braithwaite discloses that between consecutive dispensing of powder from one (or the other) of said carriers, the indexing mechanism is operable to rotate both of said carriers relative to the dispensing mechanism (page 8, ln. 1-6).

As to claim 15 and 16, Braithwaite discloses that the dispensing mechanism is operable to release powder from a pocket of each carrier for a single inhalation of both respective powders simultaneously (page 8, ln. 1-6).

As to claim 17, Braithwaite discloses that the dispensing mechanism is operable to release powder from a pocket of one of the carriers for inhalation then to release powder from the other of the carriers for inhalation (page 8, ln. 1-6).

As to claim 20 and 21, Braithwaite discloses that between consecutive dispensing of powder, the indexing mechanism is operable to rotate one of said carriers in turn between consecutive dispensing positions before rotating the other of said carriers and that the dispensing mechanism and the indexing mechanism are together operable to dispense the powder from all of the pockets from one of said carriers before dispensing powder from pockets of the other of said carders (page 10, ln. 106).

9. Claim 33 is rejected under 35 U.S.C. 102(b) as being anticipated by Pike (WO 02/024263 A3).

As to claim 33, Pike discloses a device for dispensing individual doses of powder from respective pockets of a carrier including: a chassis 2 (Fig. 1); a first support 4 mounted on the chassis 2; the first support 4 including an array of gear teeth 40 (Fig. 2) centered on the central axis, a priming member 44 (Fig. 5, Fig. 5) mounted on the chassis 2; and an intermittent motion 42 mounted on the chassis 2 (pg. 8, ln. 4-14).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Newell et al. in view of Smith et al. (US Patent Publication 2003/0183229).

Newell discloses the claimed invention (as discussed in claims 1-4 above) including that the respective first flow path connects with the second flow path downstream of the bypass (Fig. 1, Fig. 6). Newell does not disclose that the angle between the first and second flow paths is such that no powder impacts the walls defining the second flow path (less than 45 degrees). However, Smith teaches a second flow path that bypasses a pocket of medicament and is less than 45 degrees with respect to a first flow path (angle α is between 25 and 40 degrees, Fig. 5, paragraph [0102], ln. 1-9). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the second flow path of Newell to be configured to be less than 45 degrees with respect to the first flow path as taught by Smith in order to achieve adequate agglomerate break up (paragraph [0102], ln. 4-8).

12. Claims 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bonney et al. (US Patent Publication 2007/0062525) in view of Murray (EP 0 469 814 A1).

As to claim 22, Bonney discloses a device (Fig. 11a, Fig. 11b) for dispensing individual doses of powder from respective pockets 1020a of a carrier 1019a, the device including a first support 1018a (paragraph [0238]) and a first prodger member 1016a (paragraph [0239]). Bonney does not disclose a cam member adjacent to the second

side surface of a supported carrier wherein the cam member has a first side surface for engaging with the first prodger member. However, Murray teaches a cam member 30 (Fig. 1) adjacent to a side surface of a supported carrier 40 wherein the cam member 30 has a first side surface 35 for engaging a prodger member 31 (col. 3, ln. 9-21). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Bonney to include the cam member adjacent the prodger member as taught by Murray in order to provide a suitable means for rotatably actuating the prodger member.

As to claim 23, the modified device of Bonney discloses the claimed invention including a second support 1018b (Fig. 11a, 11b of Bonney), a second prodger member 1016b (Fig. 11a, 11b of Bonney) and that the cam member 30 (Fig. 1 of Murray) has a second side surface 36.

As to claim 24, Bonney discloses an indexing mechanism (paragraph [0032]).

13. Claims 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bonney et al. in view of Murray, as applied to claims 22-24 above, and further in view of Crowder et al. (US Patent No. 6,889,690).

As to claims 25 and 26, the modified device of Bonney does not disclose that when one of the prodger members is aligned with a pocket, the other prodger member is aligned between pockets. Rather, Bonney discloses that the carriers 1018a/1018b are aligned such that a pocket of each carrier is aligned with the prodger member simultaneously (paragraph [0240]). However, Crowder teaches offsetting the respective pockets of two carriers (Fig. 12A, Fig. 12B) so that only the contents of one of each

respective carrier's pockets are aligned with a prodger member 299 (col. 19, ln. 20) at a time (col. 17, ln. 56-63). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the arrangement of the carriers of Bonney to be offset as taught by Crowder in order to allow alternating dispensing of medicament from each carrier. The modified device of Bonney now discloses that the indexing mechanism and cam member are able to perform the functional limitations to the claims.

As to claim 27, the modified device of Bonney discloses the claimed limitations (i.e., a priming member 1015a, Fig. 11a/11b of Bonney).

14. Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pike in view of Harvey et al. (US Patent No. 4,317,385).

As to claim 34, Pike discloses the claimed invention except that the intermittent motion mechanism is a Geneva wheel rotatably mounted on the chassis on an axis offset from the central axis. However, Harvey discloses a Geneva wheel 11 used in an indexing mechanism to drive a cam wheel 14 whose axes are offset from one another (Fig. 1, col. 2, ln. 10-24). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to replace the intermittent motion mechanism of Pike with the Geneva wheel as taught by Harvey in order to provide a simple means for creating intermittent motion of the support through actuation of the priming mechanism.

15. Claims 35-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pike in view of Harvey et al., as applied to claim 34 above, and further in view of Braithwaite.

As to claim 35, the modified device of Pike discloses the claimed invention except for a second support mounted on the chassis and including an array of gear teeth centered on the central axis. However, Braithwaite teaches a dispensing mechanism (Fig. 7-10) with a two supports 101a/101b mounted on a chassis 114 centered on a central axis (pg. 9, ln. 6-10). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Pike to include a second support as taught by Braithwaite in order to allow two medications to be dispensed simultaneously or alternately.

As to claim 36, the modified device of Pike discloses the claimed invention including that the arrays of gear teeth 40 are incomplete circular arrays leaving respective spaces (see illustrated Fig. 3 below).

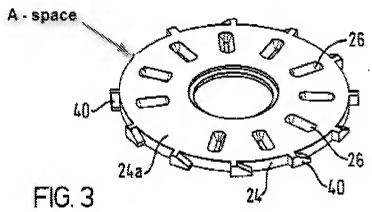

FIG. 3

As to claim 37, the modified device of Pike discloses the claimed invention except for a changeover component located between the first and second supports, the first support having a feature engaging with the changeover component and the second support having a second feature for engaging with the changeover component. However, Braithwaite teaches a changeover component 111 (Fig. 7-10) located between two supports 101a/101b and a feature 105 on each support for engaging the changeover component 111 (pg. 8, ln. 18—pg. 9, ln. 4). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Pike to include the changeover component and feature of Braithwaite in order to allow rotation of only one support at a time.

As to claim 38, the modified device of Pike discloses the structural limitations to the claim (see explanation of claim 37 above).

As to claim 39-41, the modified device of Pike discloses the claimed invention, as discussed in claims 33-38 above, including an indexing mechanism (intermittent motion mechanism discussed in claim 33 above).

As to claim 42, the modified device of Pike discloses the claimed invention including that the changeover component is supported freely between and by the first and second supports (see Fig. 7-10 of Braithwaite).

16. Claims 48-50 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rand et al. (US Patent No. 6,679,254) in view of Harrison et al. (US Patent No. 7,093,594).

As to claim 48, Rand discloses a device for dispensing individual doses of powder from respective pockets of a carrier, the device including an indexing mechanism (col. 3, ln. 21-59). Rand does not disclose a first counter ring having an indication of unit counts on a first display surface, a second counter ring having an indication of tens counts on a second display surface, or an intermittent motion mechanism. However, Harrison teaches a dose counter 176 (Fig. 10) for an inhaler that includes a first counter ring 178 having an indication of units counts on a first display surface, a second counter ring 180 having an indication of tens counts on a second display surface, and an intermittent motion mechanism ("geneva wheel", col. 8, ln. 9-35). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Rand to include the dose counter of Harrison in order to allow the patient to view the number of doses left in the device.

As to claim 49, the modified device of Rand discloses that the intermittent motion mechanism is a Geneva mechanism (col. 8, ln. 10).

As to claim 50, the modified device of Rand discloses that the second counter ring 180 is positioned within the first counter ring 178 (see Fig. 10 of Harrison), the first counter ring 178 includes a pin ("drive feature", col. 8, ln. 24) for engaging a Geneva wheel and the second counter ring 180 includes features engageable by the Geneva wheel ("the geneva wheel is directly geared to the tens wheel", col. 8, ln. 28-29).

As to claim 52, the modified device of Rand discloses the limitations of the claim (see explanation of claim 48-50 above).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VALERIE SKORUPA whose telephone number is (571)270-1479. The examiner can normally be reached on Monday - Friday, 8:00 a.m. - 5:00 p.m., EST, alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571)272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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